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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,981	08/29/2005	Lionel Vedrine	P-5753	5214
<div>7590 07/23/2007</div> <div>David W Hightet Becton Dickinson and Company 1 Becton Drive-MC 110 Franklin Lakes, NJ 07417</div>				
			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 07/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,981	Applicant(s) VEDRINE, LIONEL	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/14/2007 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The foreign reference filed May 14 2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Document FR 2 750 051 lacks a concise explanation and also needs to be resubmitted on an IDS form.

Drawings

2. The drawings were received on May 14 2007. These drawings are acceptable for the changes indicated.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for holding the needle in position, the means for holding the container in position, and the respective means for operating said means of holding the needle in position and said means of holding the container in position must be shown or the feature(s) canceled from the claim(s). Also, the pierceable zone of the piston and the body forming a distal wall perpendicular to the axis of the needle must be shown or the feature(s) canceled from the claim(s). The needle-supporting part with at least one locking means and the

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at least one tab that comprises a locking means able to engage with that of the needle-supporting part must be shown or the feature(s) canceled from the claim(s). The engagement means integral with the plunger and the at least one tab comprising the engagement means must also be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because many of the reference characters are not clear. Reference characters 21 and 27 in Figure 2 were given as example of unclear reference characters in the drawings. All of the reference characters should be checked

to make sure they are clear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because it contains legal phraseology, i.e., the use of "said" in lines 7 and 12 and the use of "means" in lines 10 and 11. Correction is required. See MPEP § 608.01(b).

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the piston being spaced from, and not in contiguous contact with, the needle with the piston being in the second configuration or position.

Claim Objections

8. Claims 7 and 8 are objected to because of the following informalities:

Claim 7 recites the limitation "said means of holding the needle in position" in lines 1-2. Claim 8 recites the limitation "said means of keeping the container in position" in line 2. There is insufficient antecedent basis for these limitations in these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, it is unclear what the phrase "to a distance" is referring to, i.e., the distal wall of the body or the projecting needle.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al (U.S. Patent No. 6,569,115).

Barker et al disclose a device for injecting a product having a body (120) with a hollow injection needle (114) and a container (170) containing the injectable product. The device also has a plunger (130) that slides in the body. The container (170) is closed at one end and is connected to the plunger (130). Means for holding the needle in position and means for holding the container in position on the forward end of the container are provided on the device. Barker et al also disclose the device as including a piston (190) engaged in the container which is so shaped that, in a first configuration, closes the container and, in a second configuration, allows product to pass out of the

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container between itself and the container. The piston is spaced from, and not in contiguous contact with, the needle (114) with the piston being in the second configuration or position (Figure 14). Respective means for operating said means of holding the needle in position and said means of holding the container in position are in the form of the displacement of the needle retainer (150) along with the release of the container (lines 18-51 of column 10 and Figure 16). The piston (190) in the second configuration as described in lines 3-17 of column 10 has a pierceable wall or zone which allows the product to pass between the piston and the container. The piston has a peripheral zone (192) which is the section of the piston which presses tightly against the wall of the container, specifically at the rim of the container, as seen in Figure 13, and which is withdrawn from the rim, as seen in Figure 14. Barker et al also disclose the device as having spring means (160). The body forms a distal wall (shown at 122) perpendicular to the axis of the needle, from which the needle projects. As to claim 7, the means for holding the needle in position also comprise a needle-supporting part with at least one locking means in the form of the outer surface of the needle (114) and at least one tab (154) that comprises a locking means, in the form of the protrusions of the tabs, able to engage with that of the needle-supporting part. The tabs (154) are moveable radially between a normal, radially inward position as seen in Figure 15 and a radially outward position, as seen in Figure 16, where a zone of the plunger moves the tab radially out. As to claim 8, the means of keeping or holding the container in position also comprise a flange (172) formed at the opposite end of the container from the closed end of the container, engagement means (144) integral with the plunger for

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connecting the flange to the plunger and at least one tab (142) comprising the engagement means and able to move in the radial direction of the plunger between a radially inward position as seen in Figure 15 and a radially outward position as seen in Figure 16.

Response to Arguments

13. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


BM

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SUPERVISORY PATENT EXAMINER

